K111893

FEB 2 8 2012

510(k) SUMMARY

VITEK® 2 *Streptococcus* Tetracycline

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jolyn Tenllado Director, Regulatory Affairs
Phone Number:	314 -731-8386
Fax Number:	314-731-8689
Date of Preparation:	July 1st, 2011

B. Device Name:

Formal/Trade Name:	VITEK® 2 *Streptococcus* Tetracycline
Classification Name:	21 CFR 866.1645 Antimicrobial Susceptibility Test Product Code LON
Common Name:	VITEK® 2 AST-ST Tetracycline

C. Predicate Device: VITEK® 2 AST-GP Amoxicillin for *S. pneumoniae* (K063597)

D. 510(k) Summary:

VITEK® 2 *Streptococcus* Tetracycline is designed for antimicrobial susceptibility testing of Streptococcus species. VITEK® 2 *Streptococcus* Tetracycline is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. Tetracycline has an antimicrobial activity against the microorganisms listed below, according to the FDA label for this antimicrobial.

Active *in vitro* and in clinical infections
Streptococcus pneumoniae
Streptococcus pyogenes
Viridans group streptococci

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK® 2 Compact Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus spp.* and clinically significant yeast.

The antimicrobial presented in VITEK® 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/mL. The VITEK® 2 AST cards are essentially miniaturized

versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The isolate to be tested is diluted to a standardized concentration with 0.45% to 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK® 2 automatically fills, seals and places the card into the incubator/reader. The VITEK® 2 Compact has a manual filling, sealing and loading operation. The VITEK® 2 Systems monitor the growth of each well in the card over a defined period of time (up to 36 hours for yeast). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK® 2 *Streptococcus* Tetracycline demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA. Issued August 28, 2009.

The Premarket Notification (510[k]) presents data in support of VITEK® 2 *Streptococcus* Tetracycline. An external evaluation was conducted with fresh and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to confirm the acceptability of VITEK® 2 *Streptococcus* Tetracycline by comparing its performance with the CLSI broth microdilution reference method. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms. VITEK® *Streptococcus* Tetracycline demonstrated acceptable performance of 96.8% overall essential agreement and 97.1% overall category agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results using both the VITEK® 2 and VITEK® 2 Compact instrument systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

bioMérieux, Inc.
c/o Jolyn Tenllado
Director, Regulatory Affairs
595 Anglum Road
Hazelwood, MO 63042

FEB 28 2012

Re: K111893
Trade Name: VITEK®2 Streptococcus Tetracycline
Regulation Number: 21 CFR §866.1645
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: LON
Dated: February 10, 2012
Received: February 13, 2012

Dear Ms. Tenllado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section

510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111893

Device Name: VITEK® 2 Streptococcus Tetracycline
(≤ 0.25 – ≥ 16 µg/mL)

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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